

## REMARKS

### **Formal Matters**

Claims 67, 68, 70, 71 and 73-74 are pending after entry of the amendments set forth herein.

Claims 13-66, 69, 72 and 75-102 are cancelled without prejudice with renewal, without intent to acquiesce to any rejection that may be applied thereon, and without the intent to abandon any subject matter encompassed therein.

Claims 67, 68 and 74 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendments to the claims is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: page 4 line 34 to page 5 line 2. Accordingly, no new matter is added.

### **Sequence Rule Compliance**

The Office Action states that the application contains sequence disclosures, and, as such, a revised sequence listing is required.

To address this rejection, the Applicants have amended the specification to delete the sequences in question. The sequences are not required to support the patentability of the instant claims.

Mark Spencer at the USPTO was consulted for interpretation of the rules with respect to consensus sequences. Mr. Spencer stated that, according to the rules, only sequences with four or more invariant amino acids are required to be listed in a sequence listing. As such, the Applicants have deleted only sequences having four or more invariant amino acids.

In view of the foregoing, the Applicants submit that they complied with the requirements of 37 C.F.R. § 1.821-1.825.

### **Biological Deposits**

Claim 72 is cancelled. As such, there are no claims currently under examination that require a biological deposit.

Accordingly, the Office's objection that the conditions for deposit do not satisfy the requirement of 37 CFR § 1.808 is rendered moot.

**Specification**

The specification is objected to as referring to table nos. 22 and greater.

The specification has been amended to remove this reference.

In view of the foregoing, withdrawal of this rejection is respectfully requested.

**Rejection of claims under 35 U.S.C. § 101/112 (Utility)**

Claims 67 - 74 are rejected under 35 U.S.C. § 101/112, as lacking patentable utility.

In making this rejection, the Office states that “The claimed nucleic acids are not supported by a specific asserted utility because none of the disclosed uses of the nucleic acids in the specification is specific” and “Applicants list a number of possible uses but fail to assert a specific utility for the claimed nucleic acids”. On the basis of these comments, the Office asserts that the claimed subject matter lacks specific, as opposed to a substantial or credible, utility.

The Applicants respectfully disagree.

The claimed polynucleotides find specific use in cancer diagnostics. This is a specific utility and is asserted in the instant specification in the section entitled “Diagnosis, Prognosis and Management of Cancer” starting on line 11 of page 36. In particular, the claimed polynucleotides may be used in the detection of lung, breast, prostate or colon cancer, as set forth in the detailed discussion of pages 37-39.

As such, contrary to the statements made by the Office in establishing this rejection, there *are* specific uses for the claimed polynucleotides set forth in the instant specification, and the Applicants *have* asserted a specific utility for the claimed nucleic acids.

No more is required to satisfy the utility requirement of 35 U.S.C. § 101, and, accordingly, this rejection may be withdrawn.

**Rejection of claims under 35 U.S.C. § 112 (Utility)**

The Applicants respectfully submit that this rejection has been addressed in the preceding section. In other words, since the claimed invention has a utility in cancer diagnostics, a skilled person would know how to use the claimed invention.

In view of the foregoing discussion, the Applicants respectfully request withdrawal of this rejection.

**Rejection of claims under 35 U.S.C. § 112 (Written Description)**

Claims 67-71 and 73-74 are rejected as failing to comply with the written requirement of 35 U.S.C. § 112.

Without wishing to acquiesce to the rejection, claim 67 has been amended to recite “An isolated polynucleotide comprising at least 100 contiguous nucleotides of SEQ ID NO:635 or complement thereof” and claims 68 and 74 have been amended to recite “comprising at least 100 contiguous nucleotides of SEQ ID NO:635”.

The Applicants respectfully submit that the claims meet the written description requirement of 35 U.S.C. § 112 since it recites a feature that is common to all polynucleotides encompassed by the claim: 100 contiguous nucleotides of SEQ ID NO:635 or complement thereof.

The Office notes that the use of the word “comprising” in the claim causes the claim to read on full length ORFs that have yet to be discovered, and, since the full-length ORF is not specifically disclosed in the specification, reasons that claim does not meet the written description requirement of 35 U.S.C. § 112.

While the Applicants don’t dispute that the claim may read on a full length ORF, the fact that a claim may read on a species that is not specifically described in the claim is not a barrier to patentability of the claim. It is well established that even in an “unpredictable art,” applicants “are *not* required to disclose *every* species encompassed by their claims . . . .”<sup>1</sup> Thus, features that apply to only some species within a generic claim – but not to *all* species encompassed by the claim – need not be described to satisfy the written description requirement. Otherwise, to claim a genus, every species within a genus would have to be explicitly described. That is not the law.<sup>2</sup>

In other words, the Applicants agree with the Office in that the claimed polynucleotides read on polynucleotides that are not specifically described in the instant specification. However, as discussed in the previous paragraph, the law does not require specific disclosure of *every* species encompassed by a claim for the claim to be patentable.

Further, since the instant claims are free of the art, the Applicants respectfully submit that the “full-length ORF” to which the Office refers would be later found species encompassed by the instant

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<sup>1</sup> *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. (BNA) 214, 218, (C.C.P.A. 1976).

<sup>2</sup> See *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 U.S.P.Q.2d (BNA) 1300, 1302 (Fed. Cir. 1991) (“Unclaimed subject matter is not subject to the disclosure requirements of § 112; the reasons are pragmatic: the disclosure would be boundless, and the pitfalls endless.”). See also *Phillips Petroleum v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1292, 6 U.S.P.Q.2d (BNA) 1065, 1074 (D. Del. 1987) (“The applicant is not required to include in his application support for matters not set forth in the claim.”), *aff’d* 865 F.2d 1247, 9 U.S.P.Q.2d (BNA) 1461 (Fed. Cir. 1989).

claims. Since it is well established that an explicit description of later-discovered species that now fall within a claimed genus is not required,<sup>3</sup> the Office's reasoning for rejecting these claims appears to be inadequate, according to the current law of written description.

In view of the foregoing, the Applicants respectfully submit that this rejection of the claims should be withdrawn without any further discussion.

**Rejection of claims under 35 U.S.C. § 112 (enablement)**

Claim 72 is rejected as failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph.

Claim 72 is cancelled, and, accordingly, this rejection is moot. Withdrawal of this rejection is respectfully requested.

**Rejection of claims under 35 U.S.C. § 112, second paragraph**

The claims are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting terms that are unclear to the Examiner.

Without wishing to acquiesce to the rejection, claim 67 has been amended to recite "An isolated polynucleotide comprising at least 100 contiguous nucleotides of SEQ ID NO:635 or complement thereof" and claims 68 and 74 have been amended to recite "comprising at least 100 contiguous nucleotides of SEQ ID NO:635".

The Applicants respectfully submit that the metes and bounds of the instant claims are clear, and, accordingly, this rejection may be withdrawn.

**Rejections of claims under 35 U.S.C. § 102**

The claims are rejected under 35 U.S.C. § 102(b) as anticipated by Hiller.

Hillier discloses a cDNA that has 89 contiguous nucleotides of SEQ ID NO:635.

Without wishing to acquiesce to the rejection, claim 67 has been amended to recite "An isolated polynucleotide comprising at least 100 contiguous nucleotides of SEQ ID NO:635 or complement

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<sup>3</sup> *Rexnord Corporation v. Laitram Corporation*, 274 F.3d 1336, 1344, 60 U.S.P.Q.2d (BNA) 1851, 1856 (Fed. Cir. 2001) ("Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."). See also *In re Hogan and Banks*, 559 F.2d 595, 605-06, 194 U.S.P.Q. (BNA) 527, 537 (C.C.P.A. 1977); *United States Steel Corporation v. Phillips Petroleum Company*, 865 F.2d 1247, 1251-52, 9 U.S.P.Q.2d (BNA) 1461, 1465 (Fed. Cir. 1989).

thereof” and claims 68 and 74 have been amended to recite “comprising at least 100 contiguous nucleotides of SEQ ID NO:635”.

Since Hillier recites a cDNA that has 89 contiguous nucleotides of SEQ ID NO:635, Hillier does not disclose a polynucleotide having at least 100 contiguous nucleotides of SEQ ID NO:635. Accordingly, the claimed polynucleotides cannot be disclosed by Hillier and this rejection may be withdrawn.

The claims are rejected under 35 U.S.C. § 102(b) as anticipated by Lin.

Lin discloses a cDNA that has 17 contiguous nucleotides of SEQ ID NO:635.

Without wishing to acquiesce to the rejection, claim 67 has been amended to recite “An isolated polynucleotide comprising at least 100 contiguous nucleotides of SEQ ID NO:635 or complement thereof” and claims 68 and 74 have been amended to recite “comprising at least 100 contiguous nucleotides of SEQ ID NO:635”.

Since Lin recites a cDNA that has 17 contiguous nucleotides of SEQ ID NO:635, Lin does not disclose a polynucleotide having at least 100 contiguous nucleotides of SEQ ID NO:635. Accordingly, the claimed polynucleotides cannot be disclosed by Lin and this rejection may be withdrawn.

CONCLUSION

If the Examiner believes a teleconference would expedite prosecution, he is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,  
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Date: 10-16-03

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